

Assembly Bill No. 1442

CHAPTER 689

An act to amend Sections 117935, 117945, 117960, 118000, 118040, and 118165 of, and to add Sections 117637, 117748, 118032, and 118033 to, the Health and Safety Code, relating to pharmaceutical waste.

[Approved by Governor September 28, 2012. Filed with
Secretary of State September 28, 2012.]

LEGISLATIVE COUNSEL'S DIGEST

AB 1442, Wieckowski. Pharmaceutical waste.

The existing Medical Waste Management Act, administered by the State Department of Public Health, regulates the management and handling of medical waste, as defined. Existing law requires that all medical waste be hauled by either a registered hazardous waste hauler or by a person with an approved limited-quantity exemption granted pursuant to specified provisions of law. Violation of these provisions of law is a crime.

This bill would define pharmaceutical waste for purposes of the Medical Waste Management Act, and would exempt a pharmaceutical waste generator or parent organization that employs health care professionals who generate pharmaceutical waste from specified medical waste hauling requirements if the generator, health care professional, or parent organization retains specified documentation and meets specified requirements and if the facility receiving the medical waste retains specified documentation and meets specified requirements. The bill would authorize pharmaceutical waste to be transported by the generator or health care professional who generated the pharmaceutical waste, a staff member of the generator or health care professional, or common carrier, as defined, pursuant to these provisions. By expanding the definition of a crime, this bill would impose a state-mandated local program.

The California Constitution requires the state to reimburse local agencies and school districts for certain costs mandated by the state. Statutory provisions establish procedures for making that reimbursement.

This bill would provide that no reimbursement is required by this act for a specified reason.

The people of the State of California do enact as follows:

SECTION 1. Section 117637 is added to the Health and Safety Code, to read:

117637. "Common carrier" means either of the following:

(a) A person or company that has a United States Department of Transportation number issued by the Federal Motor Carrier Safety Administration and is registered with the Federal Motor Carrier Safety Administration as a for-hire property carrier.

(b) A person or company that has a motor carrier of property permit issued by the Department of Motor Vehicles pursuant to the Motor Carriers of Property Permit Act (Division 14.85 (commencing with Section 34600) of the Vehicle Code) and, if applicable, a carrier identification number issued by the Department of the California Highway Patrol pursuant to Section 34507.5 of the Vehicle Code.

SEC. 2. Section 117748 is added to the Health and Safety Code, to read:

117748. (a) "Pharmaceutical waste" means any pharmaceutical, as defined in Section 117747, that is a waste, as defined in Section 25124.

(b) For purposes of this part, "pharmaceutical waste" does not include any pharmaceutical that meets either of the following criteria:

(1) The pharmaceutical is being sent out of the State of California to a reverse distributor, as defined in Section 4040.5 of the Business and Professions Code, that is licensed as a wholesaler of dangerous drugs by the California State Board of Pharmacy pursuant to Section 4161 of the Business and Professions Code.

(2) The pharmaceutical is being sent by a reverse distributor, as defined in Section 4040.5 of the Business and Professions Code, offsite for treatment and disposal in accordance with applicable laws, or to a reverse distributor that is licensed as a wholesaler of dangerous drugs by the California State Board of Pharmacy pursuant to Section 4160 of the Business and Professions Code and as a permitted transfer station if the reverse distributor is located within the State of California.

SEC. 3. Section 117935 of the Health and Safety Code is amended to read:

117935. Any small quantity generator required to register with the enforcement agency pursuant to Section 117930 shall file with the enforcement agency a medical waste management plan, on forms prescribed by the enforcement agency containing, but not limited to, all of the following:

(a) The name of the person.

(b) The business address of the person.

(c) The type of business.

(d) The types, and the estimated average monthly quantity, of medical waste generated.

(e) The type of treatment used onsite.

(f) The name and business address of the registered hazardous waste hauler used by the generator for backup treatment and disposal, for waste when the onsite treatment method is not appropriate due to the hazardous or radioactive characteristics of the waste, the name of the registered hazardous waste hauler used by the generator to have untreated medical waste removed for treatment and disposal, and, if applicable, the name of the common carrier used by the generator to transport pharmaceutical waste offsite for treatment and disposal pursuant to Section 118032.

(g) A statement indicating that the generator is hauling the medical waste generated in his or her business pursuant to Section 118030 and the name and any business address of the treatment and disposal facilities to which the waste is being hauled, if applicable.

(h) The name and business address of the registered hazardous waste hauler service provided by the building management to which the building tenants may subscribe or are required by the building management to subscribe and the name and business address of the treatment and disposal facilities used, if applicable.

(i) A statement certifying that the information provided is complete and accurate.

SEC. 4. Section 117945 of the Health and Safety Code is amended to read:

117945. Small quantity generators who are not required to register pursuant to this chapter shall maintain on file in their office all of following:

(a) An information document stating how the generator contains, stores, treats, and disposes of any medical waste generated through any act or process of the generator.

(b) Records of any medical waste transported offsite for treatment and disposal, including the quantity of waste transported, the date transported, the name of the registered hazardous waste hauler or individual hauling the waste pursuant to Section 118030, and, if applicable, the name of the common carrier transporting pharmaceutical waste pursuant to Section 118032. The small quantity generator shall maintain these records for not less than two years.

SEC. 5. Section 117960 of the Health and Safety Code is amended to read:

117960. Any large quantity generator required to register with the enforcement agency pursuant to Section 117950 shall file with the enforcement agency a medical waste management plan, on forms prescribed by the enforcement agency containing, but not limited to, all of the following:

(a) The name of the person.

(b) The business address of the person.

(c) The type of business.

(d) The types, and the estimated average monthly quantity, of medical waste generated.

(e) The type of treatment used onsite, if applicable. For generators with onsite medical waste treatment facilities, including incinerators or steam sterilizers or other treatment facilities as determined by the enforcement agency, the treatment capacity of the onsite treatment facility.

(f) The name and business address of the registered hazardous waste hauler used by the generator to have untreated medical waste removed for treatment, if applicable, and, if applicable, the name and business address of the common carrier transporting pharmaceutical waste pursuant to Section 118032.

(g) The name and business address of the registered hazardous waste hauler service provided by the building management to which the building

tenants may subscribe or are required by the building management to subscribe, if applicable.

(h) The name and business address of the offsite medical waste treatment facility to which the medical waste is being hauled, if applicable.

(i) An emergency action plan complying with regulations adopted by the department.

(j) A statement certifying that the information provided is complete and accurate.

SEC. 6. Section 118000 of the Health and Safety Code is amended to read:

118000. (a) Except as otherwise exempted pursuant to Section 118030 or 118032, all medical waste transported to an offsite medical waste treatment facility shall be transported in accordance with this chapter by a registered hazardous waste transporter issued a registration certificate pursuant to Chapter 6 (commencing with Section 118025) and Article 6.5 (commencing with Section 25167.1) of Chapter 6.5 of Division 20. A hazardous waste transporter transporting medical waste shall have a copy of the transporter's valid hazardous waste transporter registration certificate in the transporter's possession while transporting medical waste. The transporter shall show the certificate, upon demand, to any enforcement agency personnel or authorized employee of the Department of the California Highway Patrol.

(b) Except for small quantity generators transporting medical waste pursuant to Section 118030 or small quantity generators or common carriers transporting pharmaceutical waste pursuant to Section 118032, medical waste shall be transported to a permitted offsite medical waste treatment facility or a permitted transfer station in leak-resistant and fully enclosed rigid secondary containers that are then loaded into an enclosed cargo body.

(c) A person shall not transport medical waste in the same vehicle with other waste unless the medical waste is separately contained in rigid containers or kept separate by barriers from other waste, or unless all of the waste is to be handled as medical waste in accordance with this part.

(d) Medical waste shall only be transported to a permitted medical waste treatment facility, or to a transfer station or another registered generator for the purpose of consolidation before treatment and disposal, pursuant to this part.

(e) Facilities for the transfer of medical waste shall be annually inspected and issued permits in accordance with the regulations adopted pursuant to this part.

(f) Any persons manually loading or unloading containers of medical waste shall be provided by their employer at the beginning of each shift with, and shall be required to wear, clean and protective gloves and coveralls, changeable lab coats, or other protective clothing. The department may require, by regulation, other protective devices appropriate to the type of medical waste being handled.

SEC. 7. Section 118032 is added to the Health and Safety Code, to read:

118032. A pharmaceutical waste generator or parent organization that employs health care professionals who generate pharmaceutical waste is exempt from the requirements of subdivision (a) of Section 118000 if all of the following requirements are met:

(a) The generator or parent organization has on file one of the following:

(1) If the generator or parent organization is a small quantity generator required to register pursuant to Chapter 4 (commencing with Section 117915), a medical waste management plan prepared pursuant to Section 117935.

(2) If the generator or parent organization is a small quantity generator not required to register pursuant to Chapter 4 (commencing with Section 117915), the information document maintained pursuant to subdivision (a) of Section 117945.

(3) If the generator or parent organization is a large quantity generator, a medical waste management plan prepared pursuant to Section 117960.

(b) The generator or health care professional who generated the pharmaceutical waste transports the pharmaceutical waste himself or herself, or directs a member of his or her staff to transport the pharmaceutical waste to a parent organization or another health care facility for the purpose of consolidation before treatment and disposal, or contracts with a common carrier to transport the pharmaceutical waste to a permitted medical waste treatment facility or transfer station.

(c) Except as provided in subdivision (d), all of the following requirements are met:

(1) Prior to shipment of the pharmaceutical waste, the generator notifies the intended destination facility that it is shipping pharmaceutical waste to it and provides a copy of the tracking document, as specified in Section 118040.

(2) The generator and the facility receiving the pharmaceutical waste maintain the tracking document, as specified in Section 118040.

(3) The facility receiving the pharmaceutical waste notifies the generator of the receipt of the pharmaceutical waste shipment and any discrepancies between the items received and the tracking document, as specified in Section 118040, evidencing diversion of the pharmaceutical waste.

(4) The generator notifies the enforcement agency of any discrepancies between the items received and the tracking document, as specified in Section 118040, evidencing diversion of the pharmaceutical waste.

(d) (1) Notwithstanding subdivision (c), if a health care professional who generates pharmaceutical waste returns the pharmaceutical waste to the parent organization for the purpose of consolidation before treatment and disposal over a period of time, a single-page form or multiple entry log may be substituted for the tracking document, if the form or log contains all of the following information:

(A) The name of the person transporting the pharmaceutical waste.

(B) The number of containers of pharmaceutical waste. This clause does not require any generator to maintain a separate pharmaceutical waste

container for every patient or to maintain records as to the specified source of the pharmaceutical waste in any container.

(C) The date that the pharmaceutical waste was returned.

(2) The form or log described in paragraph (1) shall be maintained in the files of the health care professional who generates the pharmaceutical waste and the parent organization or another health care facility that receives the pharmaceutical waste.

(3) This subdivision does not prohibit the use of a single document to verify the return of more than one container to a parent organization or another health care facility, provided the form or log meets the requirements specified in paragraphs (1) and (2).

SEC. 8. Section 118033 is added to the Health and Safety Code, to read:

118033. The pharmaceutical waste that is separated from medical waste by the generator shall be maintained in a manner to secure the pharmaceutical waste contents from access by unauthorized individuals. Any suspected or confirmed tampering of, unauthorized access to, or loss of this pharmaceutical waste shall be reported to the appropriate state licensing authority.

SEC. 9. Section 118040 of the Health and Safety Code is amended to read:

118040. (a) Except with regard to sharps waste consolidated by a home-generated sharps consolidation point approved pursuant to Section 117904, a hazardous waste transporter or generator transporting medical waste shall maintain a completed tracking document of all medical waste removed for treatment or disposal. A hazardous waste transporter or generator who transports medical waste to a facility, other than the final medical waste treatment facility, shall also maintain tracking documents which show the name, address, and telephone number of the medical waste generator, for purposes of tracking the generator of medical waste when the waste is transported to the final medical waste treatment facility. At the time that the medical waste is received by a hazardous waste transporter, the transporter shall provide the medical waste generator with a copy of the tracking document for the generator's medical waste records. The transporter or generator transporting medical waste shall maintain its copy of the tracking document for three years.

(b) The tracking document shall include, but not be limited to, all of the following information:

(1) The name, address, telephone number, and registration number of the transporter, unless transported pursuant to Section 118030.

(2) The type of medical waste transported and the quantity or aggregate weight of medical waste transported.

(3) The name, address, and telephone number of the generator.

(4) The name, address, telephone number, permit number, and the signature of an authorized representative of the permitted facility receiving the medical waste.

(5) The date that the medical waste is collected or removed from the generator's facility, the date that the medical waste is received by the transfer

station, the registered large quantity generator, or point of consolidation, if applicable, and the date that the medical waste is received by the treatment facility.

(c) Any hazardous waste transporter or generator transporting medical waste in a vehicle shall have a tracking document in his or her possession while transporting the medical waste. The tracking document shall be shown upon demand to any enforcement agency personnel or officer of the Department of the California Highway Patrol. If the medical waste is transported by rail, vessel, or air, the railroad corporation, vessel operator, or airline shall enter on the shipping papers any information concerning the medical waste that the enforcement agency may require.

(d) A hazardous waste transporter or a generator transporting medical waste shall provide the facility receiving the medical waste with the original tracking document.

(e) Each hazardous waste transporter and each medical waste treatment facility shall provide tracking data periodically and in a format as determined by the department.

(f) Medical waste transported out of state shall be consigned to a permitted medical waste treatment facility in the receiving state. If there is no permitted medical waste treatment facility in the receiving state or if the medical waste is crossing an international border, the medical waste shall be treated in accordance with Chapter 8 (commencing with Section 118215) prior to being transported out of the state.

SEC. 10. Section 118165 of the Health and Safety Code is amended to read:

118165. On and after April 1, 1991, all persons operating a medical waste treatment facility shall maintain individual records for a period of three years and shall report or submit to the enforcement agency upon request, all of the following information:

- (a) The type of treatment facility and its capacity.
- (b) All treatment facility operating records.
- (c) Copies of the tracking documents for all medical waste it receives for treatment from offsite generators, hazardous waste haulers, or, pursuant to Section 118032, common carriers.

SEC. 11. No reimbursement is required by this act pursuant to Section 6 of Article XIII B of the California Constitution because the only costs that may be incurred by a local agency or school district will be incurred because this act creates a new crime or infraction, eliminates a crime or infraction, or changes the penalty for a crime or infraction, within the meaning of Section 17556 of the Government Code, or changes the definition of a crime within the meaning of Section 6 of Article XIII B of the California Constitution.